

ELIQUIS® (apixaban) Meets Primary and Key Secondary Endpoints in Phase 3 ARISTOTLE Study

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Detailed Results to be Presented at European Society of Cardiology Congress 2011

[\(BUSINESS WIRE\)](#)--[Bristol-Myers Squibb Company](#) (NYSE: BMY) and [Pfizer Inc.](#) (NYSE: PFE) announced today topline results of the Phase 3 ARISTOTLE trial of ELIQUIS®. In this study of patients with atrial fibrillation and at least one additional risk factor for stroke, ELIQUIS met the primary efficacy objective of non-inferiority to warfarin on the combined outcome of stroke (ischemic, hemorrhagic or unspecified type) and systemic embolism. In addition, ELIQUIS met the key secondary endpoints of superiority on efficacy and on ISTH (International Society on Thrombosis and Hemostasis) major bleeding compared to warfarin.

ELIQUIS, a new oral direct Factor Xa inhibitor, is being developed by the alliance of Bristol-Myers Squibb and Pfizer.

The companies expect to submit regulatory filings in atrial fibrillation in the U.S. and Europe in the third or fourth quarter of 2011.

The detailed results of the ARISTOTLE study will be presented during the “Hot Line” session on August 28, 2011, at the European Society of Cardiology Congress 2011 in Paris.

About ARISTOTLE

ARISTOTLE, a double-blind, multicenter, head-to-head Phase 3 trial, randomized 18,201 patients with atrial fibrillation from over 1,000 centers in about 40 countries. Patients were randomized to receive either ELIQUIS 5 mg twice daily (2.5 mg twice daily in selected patients) or dose-adjusted warfarin (titrated to a target INR range of 2.0 to 3.0).

About ELIQUIS

ELIQUIS is the approved trade name for apixaban in Europe and the proposed trade name in the U.S. and other countries. ELIQUIS is not approved for the prevention of stroke in patients with atrial fibrillation. Bristol-Myers Squibb and Pfizer recently announced the first regulatory approval for ELIQUIS for the prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery in the 27 countries of the European Union (EU).

ELIQUIS is being investigated within the EXPANSE Clinical Trials Program, which is projected to include nearly 60,000 patients worldwide across multiple indications and patient populations and includes a total of nine completed or ongoing, randomized, double-blind Phase 3 trials, including ARISTOTLE.

In addition to stroke prevention in patients with atrial fibrillation and the prevention of VTE in patients who have undergone total hip or total knee replacement surgery, ELIQUIS is being investigated in Phase 3 trials for the treatment of VTE and the prevention of VTE in hospitalized acutely ill medical patients.

About the Bristol-Myers Squibb/Pfizer Collaboration

In 2007, Pfizer and Bristol-Myers Squibb entered into a worldwide collaboration to develop and commercialize ELIQUIS, an investigational oral anticoagulant discovered by Bristol-Myers Squibb. This global alliance combines Bristol-Myers Squibb's long-standing strengths in cardiovascular drug development and commercialization with Pfizer's global scale and expertise in this field.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information, please visit <http://www.bms.com> or follow us on Twitter at <http://twitter.com/bmsnews>.

Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us.

Bristol-Myers Squibb Forward-Looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding product development. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that the companies will submit regulatory filings in the U.S. and Europe for apixaban for an indication in stroke prevention in patients with atrial fibrillation in the time frame described in this release or that apixaban will receive regulatory approval for such indication. There is also no guarantee that, if approved in this indication, apixaban will become a commercially successful product. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2010, in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

PFIZER DISCLOSURE NOTICE:

The information contained in this release is as of June 22, 2011. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about various potential indications for ELIQUIS (apixaban), including their potential benefits and the anticipated timing of submission of regulatory filings in the U.S. and EU for the atrial fibrillation indication, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial completion dates and regulatory submission dates; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for any such indications as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of any such indications; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and in its reports on Form 10-Q and Form 8-K.

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